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WITNESS my hand this
Eleventh day of May 2004

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A MASK SYSTEM

FIELD OF THE INVENTION

The invention relates to a mask system for use with positive pressure ventilation of sleep disordered breathing. In particular, the invention relates to a low cost mask system.

BACKGROUND

Obstructive Sleep Apnea (OSA) is a condition characterised by repetitive obstruction of the upper airway often resulting in oxygen desaturation and arousals from sleep. The classic daytime manifestation is excessive sleepiness but other symptoms such as unrefreshing sleep, poor concentration and fatigue are commonly reported (*Sleep-Related Breathing Disorders in Adults-AASM Task Force*, Sleep 22, 1999)

The use of nasal continuous positive airway pressure (CPAP) to treat OSA was taught by Sullivan in US Patent 4,944,310. Other developments are taught in US Patent 5,704,345; 6,029,665 and 6,363,933.

Nasal CPAP systems typically comprise a flow generator, air tubing, and a patient interface (for example, a nasal mask). The flow generator provides a supply of air at positive pressure.

A variety of mask systems are known for use in treating sleep disordered breathing (SDB), such as the BUBBLE mask®, MIRAGE®, ULTRA MIRAGE®, and MIRAGE VISTA™ masks, all manufactured by ResMed Limited.

Another known mask is the Weinmann nasal mask.

A mask system typically comprises headgear and a mask assembly. The headgear is used to hold and position the mask on the face of a patient. The mask assembly typically comprises at least a rigid shell and a soft face-contacting cushion. Some mask assemblies also include elbows, vents, headgear clips, forehead supports.

A number of cushions have been patented, for example see US Patents 6,112,746; 6,357,441; 6,513,526; as have forehead supports (See US Patents 6,119,693; 6,463,931; 6,520,182; 6,532,961), headgear connectors (US Patent 6,374,826), mask ports (US Patents 6,439,230), and cushion clips (US Patent 6,412,487). The contents of all these patents are hereby incorporated by cross-reference.

One known mask assembly the PAPILLION™ mask, manufactured by MAP, Germany is shown in Austrian Design Registrations #50770 and #50771 (and pending US Design Patent 29/163,978 and Australian Design Registration Application 2153/2002). This mask assembly comprises a combination silicone shell/cushion, a frame, and a joining member coupled to an adjustable T-bar forehead support. An air delivery tube is connected over the forehead of a patient in a manner similar to the configuration of MIRAGE® mask, manufactured by ResMed Limited.

Since mask systems for treating sleep disordered breathing have to be worn for several hours every night while a patient sleeps, it is important that that mask system be comfortable. In particular, it is important that any patient contacting portions of the mask system do not lead to pressure sores on a patient's face.

A problem which can occur in prior art mask systems is that there can be drag forces from the tube which when transferred through the elbow can disrupt the seal of the cushion on the face.

One solution to this problem is found in US 6,039,044. It is an object of the invention to provide at least an alternative solution to this problem.

A difficulty with some prior art mask assemblies is that those which achieve a clinically effective seal while being comfortable to wear each night at home can be expensive to manufacture. Headgear can represent a significant proportion of the cost of manufacturing a mask system. The manufacturing costs are passed onto customers which leads to a more expensive mask assembly for patients. This may in turn mean that fewer patients can afford treatment. This may also mean that there can be a tendency for clinics and hospitals to reuse masks among numerous patients. Unless thorough hygiene systems are put in place to manage cross-infection it is not advised that a mask be re-used by different patients. In general,

particularly in hospitals with the advent of respiratory diseases such as SARS, it is desirable to have a mask system which is cheap enough to be disposable.

It is a further object of the invention to provide a low cost mask assembly for treating sleep disordered breathing.

It is a further object of the invention to provide a disposable mask assembly for treating sleep disordered breathing.

SUMMARY

In accordance with a first aspect of the invention, there is provided a comfortable low cost mask system comprising headgear, a shell/cushion, a frame, elbow and retaining ring.

In accordance with another aspect of the invention, there is provided a low cost headgear.

In accordance with another aspect of the invention, there is provided a comfortable shell/cushion which has a reduced tendency to cause pressure points on a patient's face.

BRIEF DESCRIPTION OF FIGURES

Fig. 1a shows a perspective view of a mask system in accordance with a second embodiment of the invention.

Fig. 1b shows a front perspective view of a mask assembly in accordance with a first embodiment of the invention.

Fig. 2 shows a front view of the mask assembly of Fig. 1b

Fig. 3 shows a side view of the mask assembly of Fig. 1b

Fig. 4 shows a rear view of the mask assembly of Fig. 1b

Fig. 5 shows a bottom view of the mask assembly of Fig. 1b

Fig. 6 shows a top view of the mask assembly of Fig. 1b

Fig. 7 shows an exploded view of a mask assembly in accordance with a second embodiment of the invention.

Fig. 8 shows a cross-section of the mask assembly of Fig. 1b

Fig. 9 shows a further cross-section of the mask assembly of Fig. 1b superimposed over a side view.

Fig. 10 shows a front perspective view of a mask assembly in accordance with a third embodiment of the invention.

Fig. 11 shows an exploded view of the mask assembly of Fig. 10 near the face of a patient.

Fig. 12 shows a side view of the mask assembly of Fig. 10 including disposable headgear in use.

Fig. 13 to Fig. 20 show various views of a frame in accordance with a first embodiment of the invention.

Fig. 21 to Fig. 25 show various views of a frame in accordance with a third embodiment of the invention.

Fig. 26 to Fig. 29 show various views of a retainer ring in accordance with an embodiment of the invention.

Fig. 30 to Fig. 37 show various views of an elbow in accordance with reusable embodiment of the invention.

Fig. 38 to Fig. 46 show various views of an elbow in accordance with a disposable embodiment of the invention.

Fig. 47 to Fig. 55 show various views of shell/cushion in accordance with a first embodiment of the invention.

Fig. 56 to Fig. 61 show various views of a shell/cushion in accordance with a second embodiment of the invention.

Fig. 62 to Fig. 66 show a series of cross-sectional views of a mask assembly in accordance with a second embodiment of the invention.

Fig. 67 shows headgear in accordance with a disposable embodiment of the invention.

Fig. 68 shows an alternative embodiment of the invention demonstrating decoupling of the torque transfer between the elbow and the cushion.

DETAILED DESCRIPTION OF THE INVENTION

§ 1 Introduction

In accordance with the objects of the invention a comfortable low cost mask system is provided which has few components and for example, has a single walled cushion and does not include a forehead support, nor headgear clips.

A mask system in accordance with an embodiment of the invention provides a patient interface with a range of interchangeable sub-components as part of a device for delivering a supply of air at positive pressure to the airways of a patient in the treatment of sleep disordered breathing. The mask system includes headgear and a mask assembly. See Fig. 1a. A mask assembly **10** in accordance with the invention comprises the following components: a shell/cushion **30**, a frame **40**, an elbow **50** and a retainer ring **60**. See Fig. 1b to Fig. 6. An exploded view of a mask assembly **12** in accordance with the invention is shown in Fig. 7. The mask assembly of Fig. 7 includes an alternative embodiment of shell/cushion **200**.

§ 2 Headgear

The headgear **20** is composed of 3 separate pieces of the same white non-latex elastic tape joined together to form a 3 point headgear. Headgear is attached to the frame via the button holes in the tape. Table 1 shows the dimensions of each of the straps. All ends may be cut using a hot knife to avoid fraying. 3 long strap ends may be cut at an angle of 30°/60°. Button holes (4mm ±0.5) are placed in the middle along the entire length of the straps with gaps between two button holes 5mm ±1. The tape is 20mm wide and constructed from a knitted 70% polyester and 30% non-latex elastomer. One form of suitable material is CLEERSPAN™, manufactured by the Globe Manufacturing Company. This material is suitable for a disposable mask system.

Headgear can represent a significant cost in the manufacture of a mask system and this particular low cost material can lead to a significant cost saving for the headgear and the mask system as a whole.

In a reusable form, the headgear is moulded in a number of parts and joined together with buttons or similar. In another form the reusable headgear is moulded in one piece.

Fig. 67 shows headgear in accordance with one embodiment of the invention. Fig. 12 shows headgear in use on a model head.

Strap length (mm)	*Quantity*
580	1
435	1
195	1

Table 1

§ 3 Shell/Cushion

The shell/cushion **30** defines a nose-receiving cavity and forms a seal with the face of the patient. The shell/cushion **30** has a rearward aperture through which the nose passes in use and a front aperture to which an elbow is attached. In a preferred form, the shell/cushion **30** is single walled, however in other forms it may have two or more walls, similar to a MIRAGE® mask and as taught in US Patent 6,112,746. The shell/cushion **30** forms both a sealing structure and a support structure. It may be moulded from such materials as silicone (for example LSR, Dow Corning, SILASTIC™ 94-595-HC (P/No 2666031)) or a thermoplastic elastomer.

The shell/cushion **30** has a face contacting side adapted to form a seal on a patient's face. The face contacting side includes a nasal bridge region, side regions and a lip region. The face contacting side is similar in shape to the face contacting side of the PAPILLION™ mask (manufactured by MAP GmbH) and the MIRAGE™ mask (manufactured by ResMed Limited). A range of shell/cushion **30** sizes may be provided to suit different sizes of noses. For example, in one form, shell/cushions can have shallow nasal bridge regions.

The shell/cushion **30** includes a frame-receiving channel **140** defined by a front flange **34** and a rear flange **36**. A first embodiment of shell/cushion **30** having a three point front flange of a

frame-receiving channel is shown in Fig. 47-55. A second embodiment of a shell/cushion **30** having a continuous front flange of a frame-receiving channel is shown in Fig. 56-61. In one form the front flange extends 75% to 100%, preferably 100% of the way around the perimeter, as shown in Fig. 56-61. An advantage of the front flange extending 75%-100% of the way around the perimeter is that it is less likely to be removed by inadvertence.

As shown in Fig. 4, 8, 9, 48, 49, 57, & 62-66 a rear flange of the frame-receiving cushion has different thickness in different regions. It is thinner in the nasal bridge regions than in the lower side region and the lip region. The flange is between 1-3mm thick, preferably 2mm thick. This provides sufficient support for the sealing part of the cushion in the nasal bridge region but doesn't lead to the creation of a "knife-edge" which can be uncomfortable for a patient. If the sealing part of the cushion collapses, the harder, thicker portion of the shell/cushion can create a pressure sore on the patient's face with prolonged use. Fig. 63 and 64 show sections from Fig. 62 with thicker rear flange regions, whereas the sections in Fig. 65 and 66 have thinner rear flange regions.

The shell/cushion includes a vent which in a preferred form comprises four orifices. As shown in Fig. 3 these are positioned at an angle with respect to the elbow. In another form, the vent orifices are constructed at a flatter angle, for example, 10-15° from the vertical (with respect to the orientation shown in Fig. 3. When a patient is wearing the mask and lying down, the vent orifices will be aligned generally at 10-15° from the horizontal).

Fig. 52 shows a detail of a cross-section of the front aperture showing a portion of the region where the retaining ring is inserted. In one form for use in a disposable mask, this region is designed with a thin walled section **522** adjacent the channel **524**. The thin walled section **522** is designed to tear if one attempts to remove the elbow, for example to wash the elbow. This aspect represents a safety feature preventing re-use of a disposable mask, reducing the likelihood of cross-infection.

The method of assembly of the mask with the second embodiment of cushion **200** will now be described. The frame **40** is adapted to be pushed into position on the shell/cushion **30** from the front of the shell/cushion **30** and engage with a channel **140** on the shell/cushion **30**. The retainer

ring **60** is adapted to engage with a channel **250** on the shell/cushion **30**. The process is similar for the first embodiment.

The connection between the elbow **50**, retaining ring **60** and shell/cushion **30** can be seen in the cross-section views of the assembly, Fig. 8 and Fig. 9. The ring **60** comprises a cylinder **62**, a front flange **64** and a rear flange **66**. The rear flange **66** is adapted to be inserted and retained within in a corresponding channel **524** adjacent the front aperture of a cushion/shell **30**. An undercut on an elbow **50** is adapted to engage with a rear surface **65** of the front flange **64**, thus retaining the elbow **50**. A seal is formed between a flap **526** on a shell/cushion **30** and a proximal end **32** of an elbow **50**. In this way, a leak problem with previous mask systems is overcome, since the cushion flap **526** extends over the proximal end of the elbow in an annular fashion resulting in a conformable seal between the shell/cushion and elbow.

Fig. 68 shows an alternative embodiment of shell/cushion. In this shell/cushion small bellows or a flexible neck is introduced where the elbow fits into the cushion. This flexible element allows for movement between the elbow and cushion. In this arrangement there is decoupling of the torque transfer between the elbow and the cushion

§ 4 Frame

The frame **40** is adapted to be mounted on the shell/cushion and provides anchor points **132** for headgear. A first embodiment of frame **40** providing three anchor points **132** is shown in Fig. 13-20. A second embodiment of frame **40** providing up to five anchor points is shown in Fig. 21-25. In the second embodiment of frame **40**, an alternative form of headgear with five straps, rather that the three strap embodiment shown in Fig. 1b and Fig. 67 may be used.

Fig. 18 shows a detailed view of an anchor point in cross-section from Fig. 14. In use, a patient selects the appropriate button hole of the headgear and then passes it over an anchor point on the frame **40** to set the headgear strap at the appropriate length.

The frame **40** is generally triangularly shaped having a base approximately 90mm wide and a height of approximately 84mm. Other dimensions are as indicated on the figures.

The frame may be made to any suitable configuration of anchor points so as to provide a variety of fittings to suit the particular needs of individual uses. In this regard, the placement of anchor points may be changed in a manner described in the published PCT patent application WO 02/45784, the contents of which are hereby incorporated by cross-reference. In this way the adaptability of the mask system is enhanced as the mask frame is relatively inexpensive to manufacture.

The frame **40** may be moulded from polycarbonate.

§ 5 Elbow

A distal end **52** of the elbow **50** is adapted to engage with an air delivery conduit (not shown), or a swivel and a proximal end of the elbow **50** engages with both the shell/cushion and a retainer ring positioned within the shell/cushion. An inner edge of the proximal end of the elbow **50** includes undercuts to engage with the retainer ring.

A first embodiment of elbow **50** is shown in Fig. 30-37. The shape and dimensions of an embodiment of the elbow are indicated on the figures. This first embodiment includes finger grips **54** to enable the elbow **50** to be removed for cleaning. The first embodiment has two undercuts to removably engage with the retainer ring.

A second embodiment of elbow is shown in Fig. 38-46. This second embodiment does not include the finger grips **54** of the first embodiment and has undercuts all the way around the inner edge. In this way it is adapted to be not removable from the shell/cushion and is thus useful for a disposable mask.

The elbow may be preferably moulded from polycarbonate or polypropylene.

In a preferred form the elbow **50** includes a port **56** to enable access to the interior of the mask shell/cushion. For example, a pressure sensor may be attached. A polypropylene or silicone cap may be used to cover and seal the port when not in use.

The elbow **50** is not designed to freely rotate, but includes a braking system. This means that, while adjustable, it tends to remain in the position in which it has been set. This is achieved through the combination of sizes shown and the use of one material on the elbow **50** and a different material on the cushion/shell with which it engages. This can be achieved through a slightly interfering fit between the elbow and cushion.

Preferably a suitable combination of materials and component configurations are selected so as to allow the user by hand to easily rotate the elbow to any desired position and once positioned, the elbow will not move when experiencing the forces which are applied when the mask is attached to the gas conduit and it is in use by a sleeping patient. This aspect of the invention allows the user to position the elbow and thereby the gas conduit relative to the mask and face that is personally preferred.

The elbow **50** and frame **40** are not directly connected, since their contact is through the shell/cushion. Since the shell/cushion is constructed from a flexible material, movement of an air delivery conduit attached to the swivel elbow does not directly disrupt the seal of the shell/cushion. In this way, decoupling of drag forces from the air delivery conduit can be achieved.

Fig. 68 shows an alternative embodiment in which decoupling of the forces from the air delivery conduit can be achieved.

In other aspects, the elbow is generally similar to that found on the MIRAGE VISTA mask, manufactured by ResMed Limited.

§ 6 Retainer ring

A retainer ring **60** for use with the mask assembly is show in Fig. 26-29. The ring may be constructed from polycarbonate. In a preferred form the ring has an outer diameter of approximately 33mm and a thickness of 9mm. Other dimensions are shown in Fig. 27. Fig. 8 & 9 show how the retaining ring is positioned in the mask assembly in use.

In another form the retaining ring has a symmetrical configuration so that it can be inserted in either orientation.

Although the invention has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the application of the principles of the invention. Numerous modifications may be made therein and other arrangements may be devised without departing from the spirit and scope of the invention.

CLAIMS

1. A mask system for treating sleep disordered breathing comprising headgear, a shell/cushion including a channel adjacent a front aperture, a frame, an elbow including at least one undercut on a proximal end and a retaining ring including a rear flange adapted to be retainably insertable in the channel of the shell/cushion and a front flange adapted to retainably engage with the at least one undercut of the elbow.

2. A mask system as claimed in claim 1 further comprising a thin walled section adjacent the channel of the shell/cushion which is adapted to tear upon removal of the elbow.

3. A mask system for treating sleep disordered breathing comprising headgear, a frame, and shell/cushion including a frame-receiving channel defined by a front flange and a rear flange, the front flange extending 75% to 100% of the way around the perimeter of the shell/cushion, wherein the frame is adapted to be removable insertable in the frame-receiving channel of the shell/cushion.

4. A mask system as claimed in claim 3 wherein in at least a nasal bridge region of the shell/cushion adapted to contact the nasal bridge region of a patient the rear flange is from 1mm to 3mm thick.

5. A mask system as claimed in claim 4 wherein the rear flange is approximately 2mm thick.

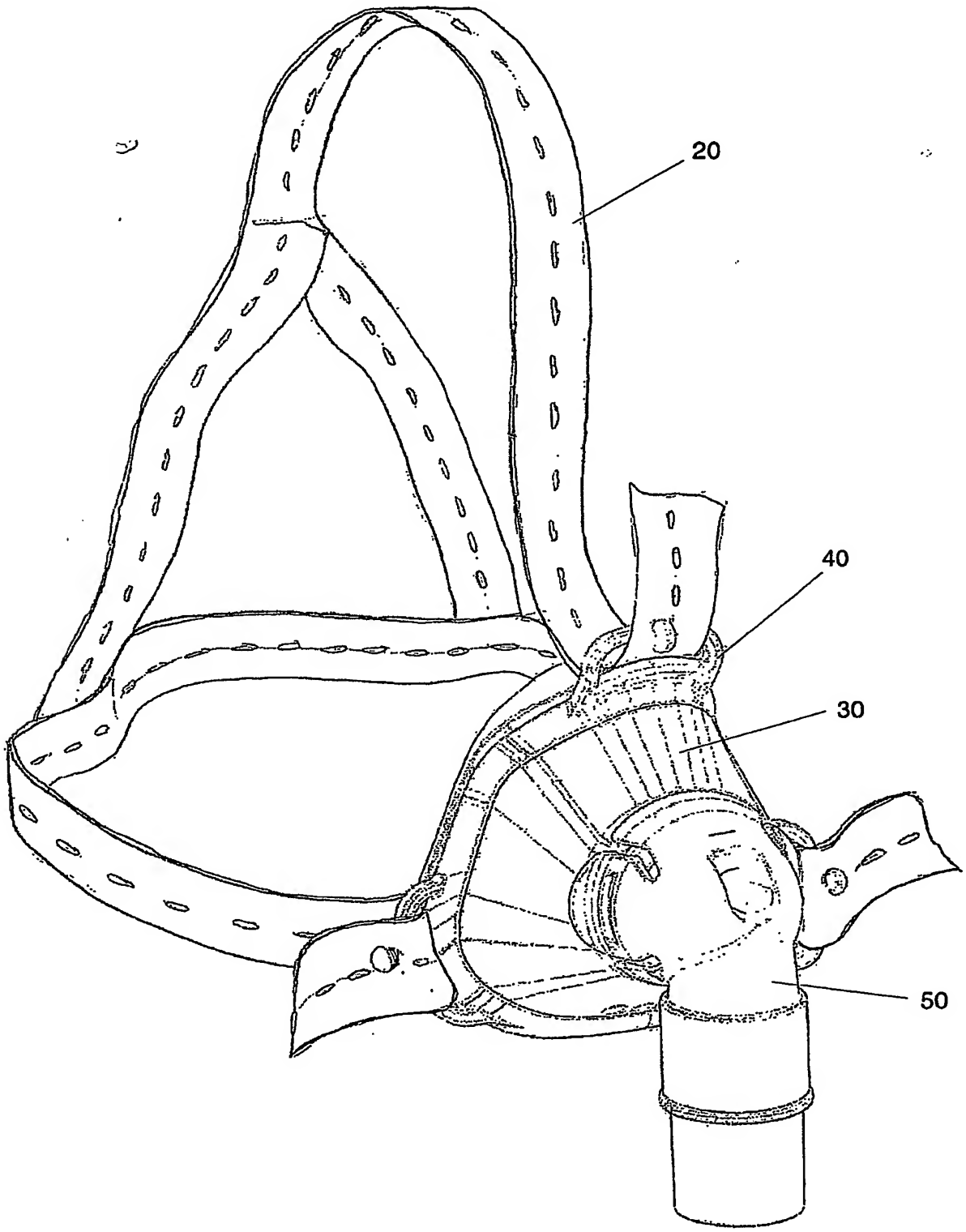

Fig. 1a

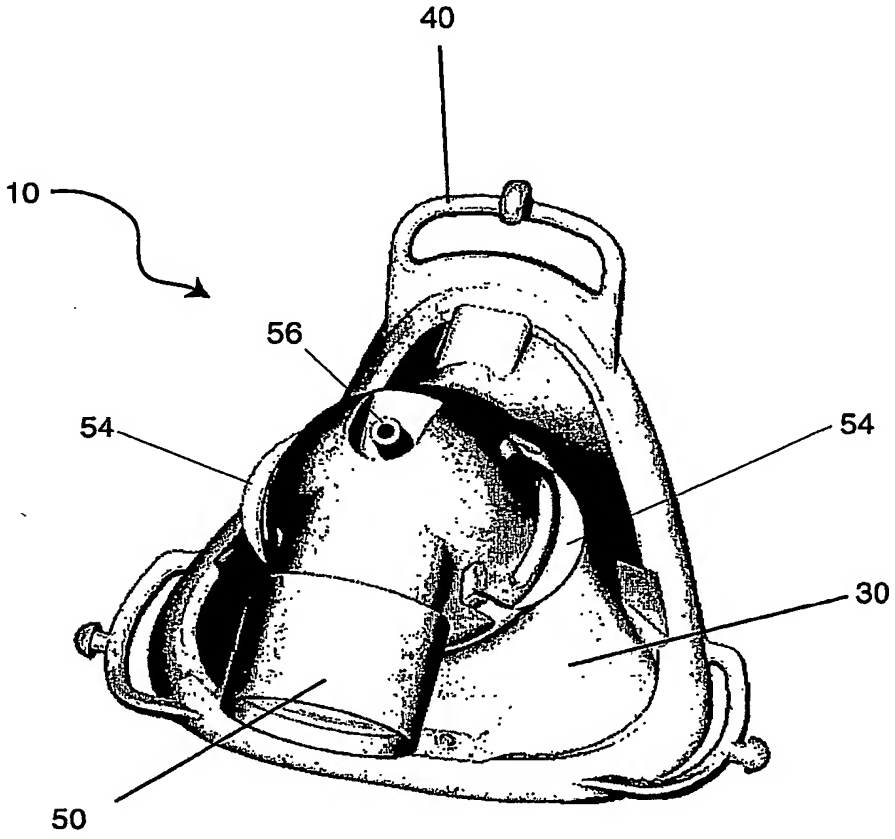

Fig. 1b

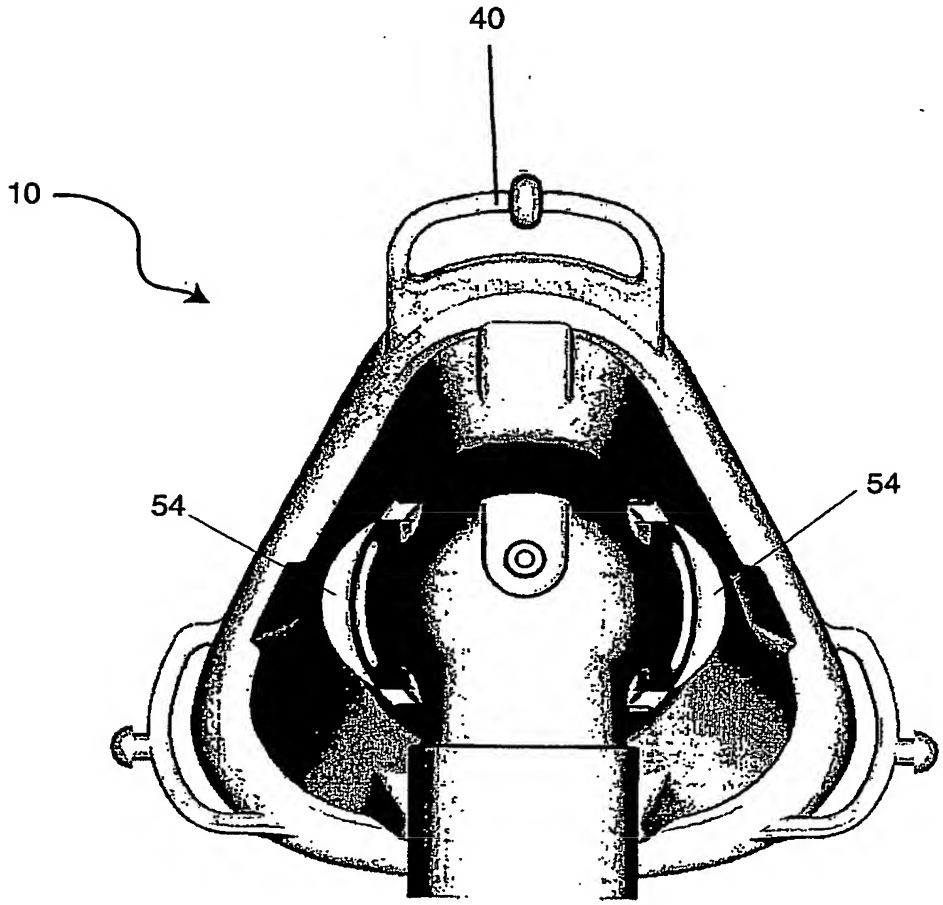

Fig. 2

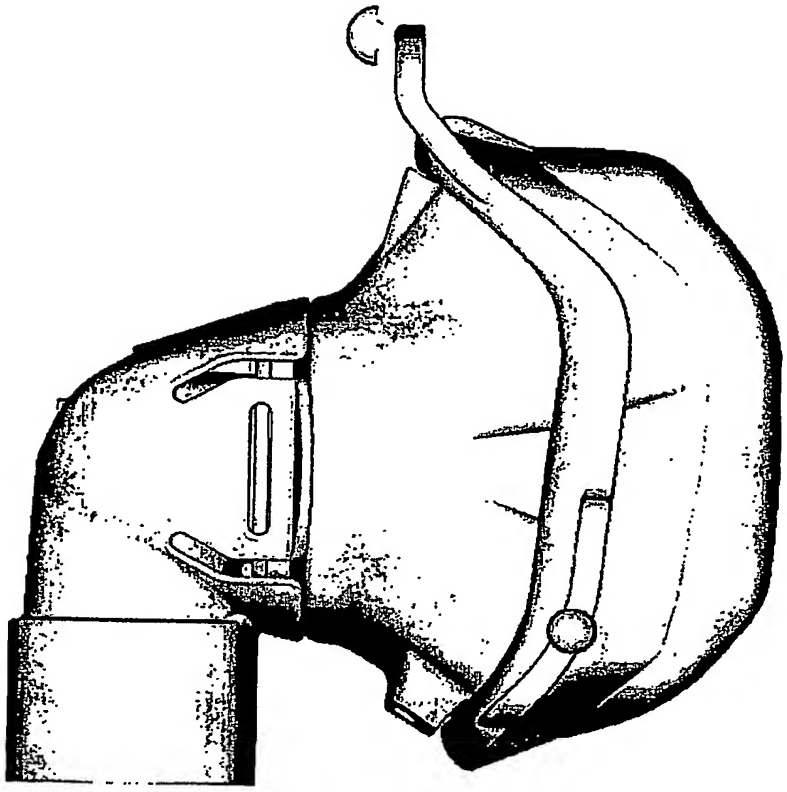

Fig. 3

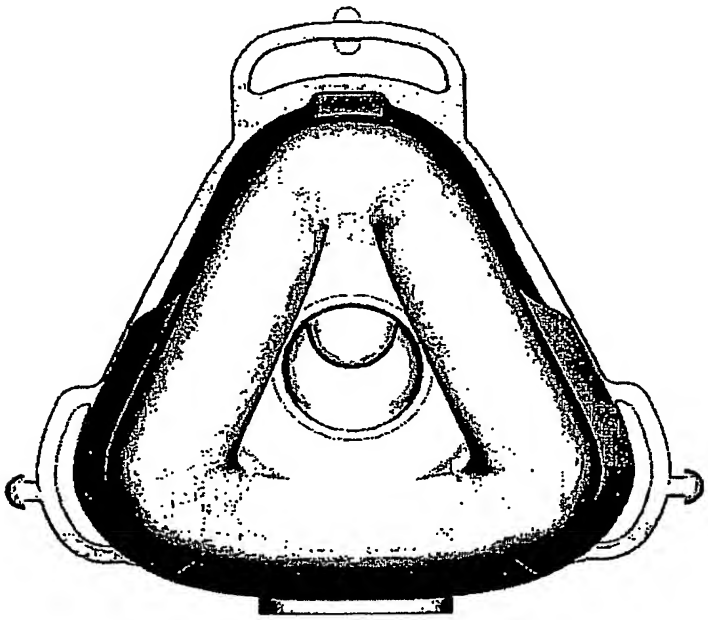

Fig. 4

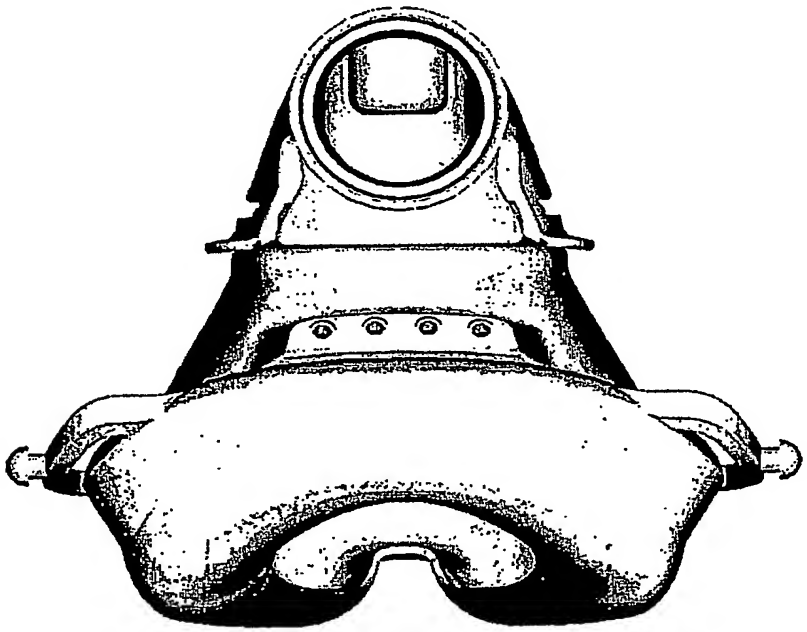

Fig. 5

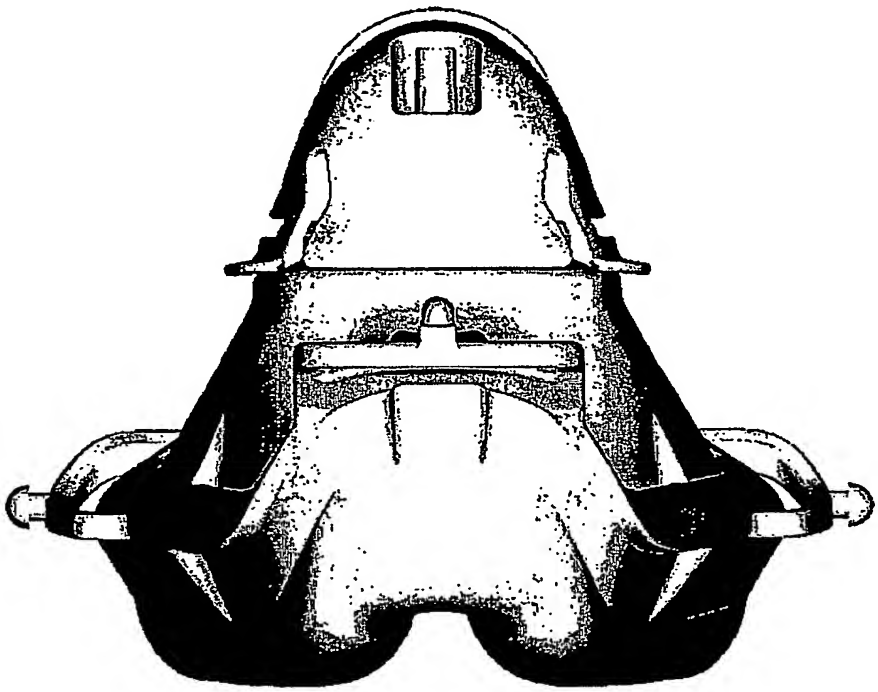

Fig. 6

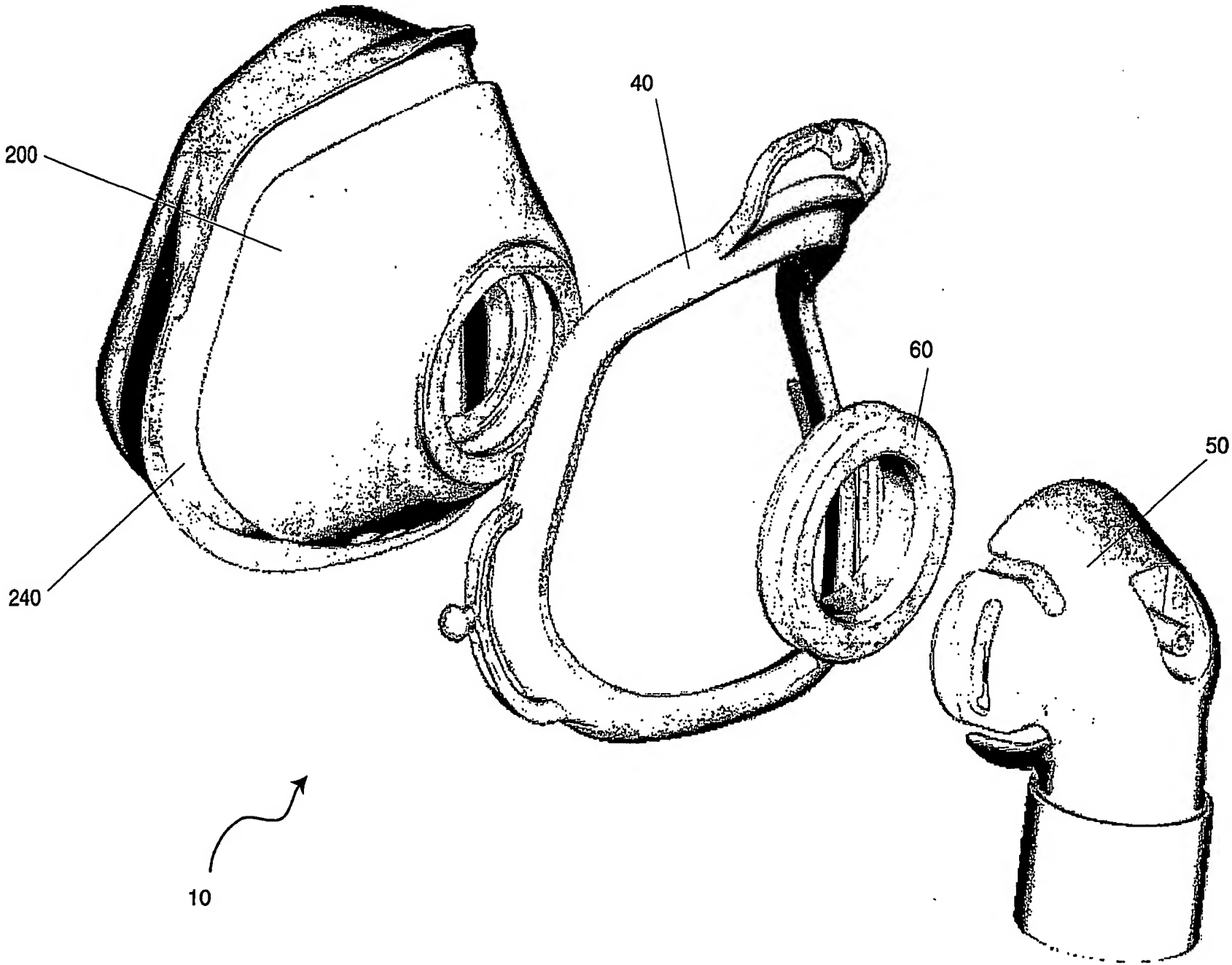

Fig. 7

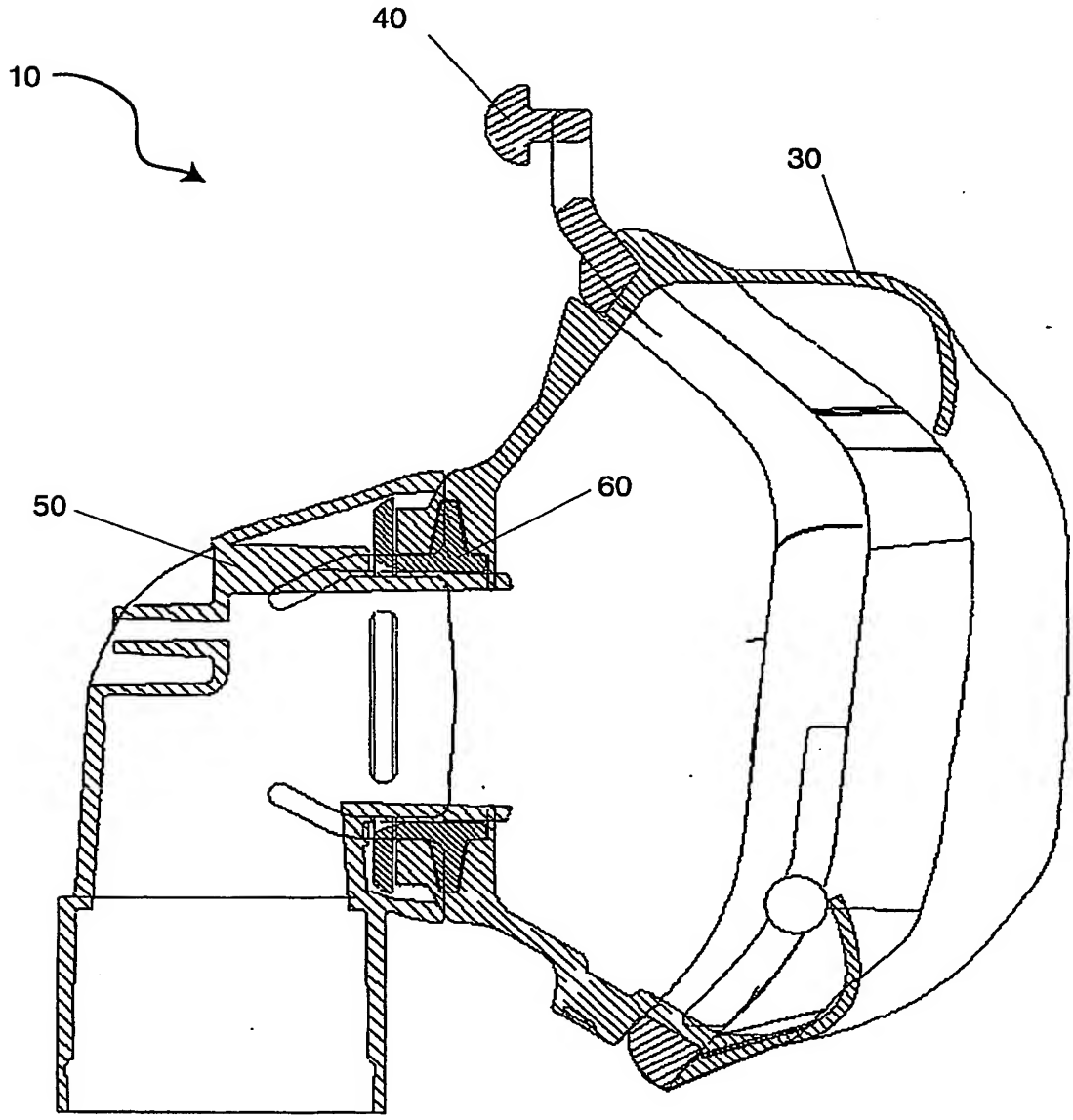

Fig. 8

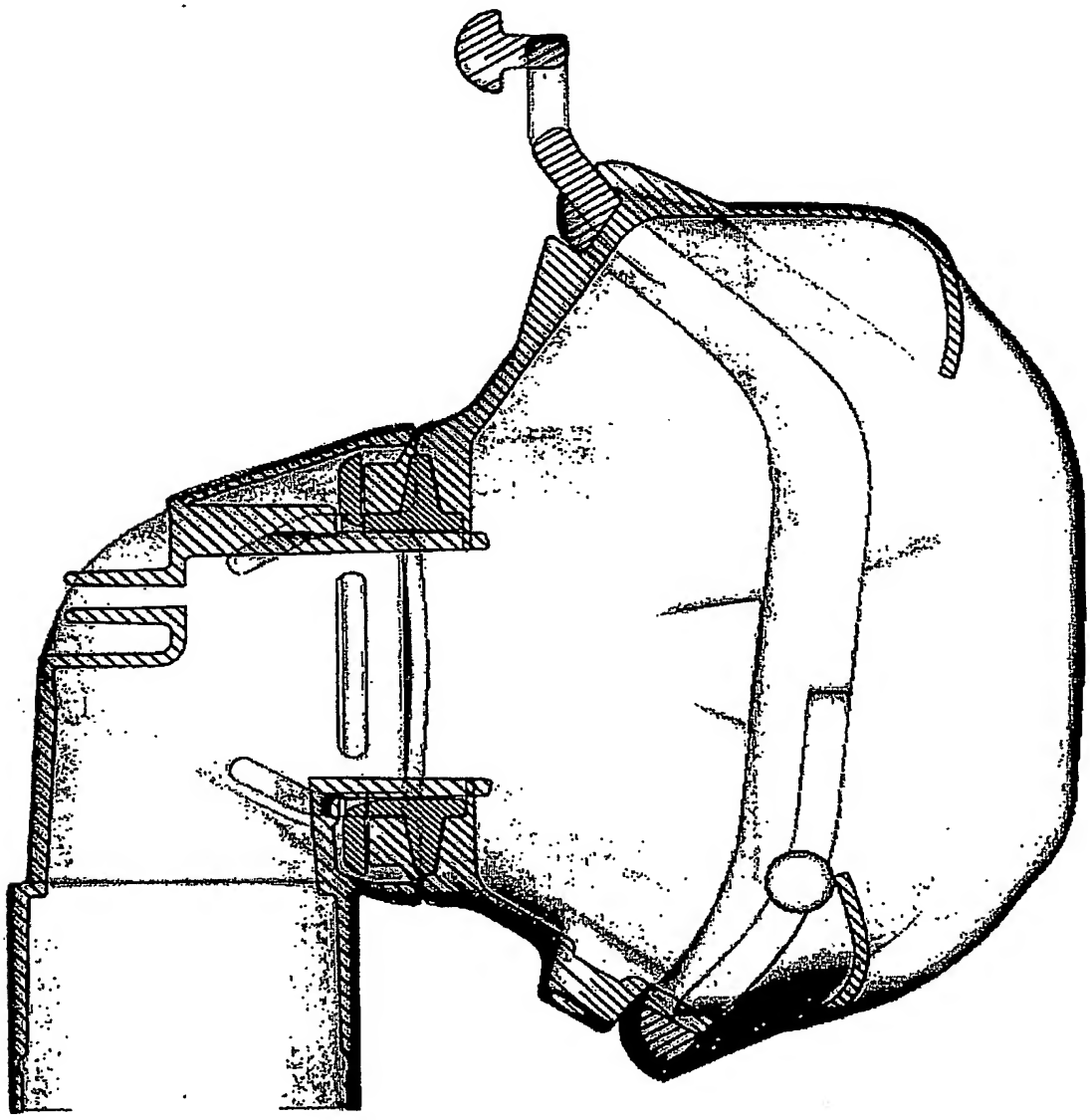

Fig. 9

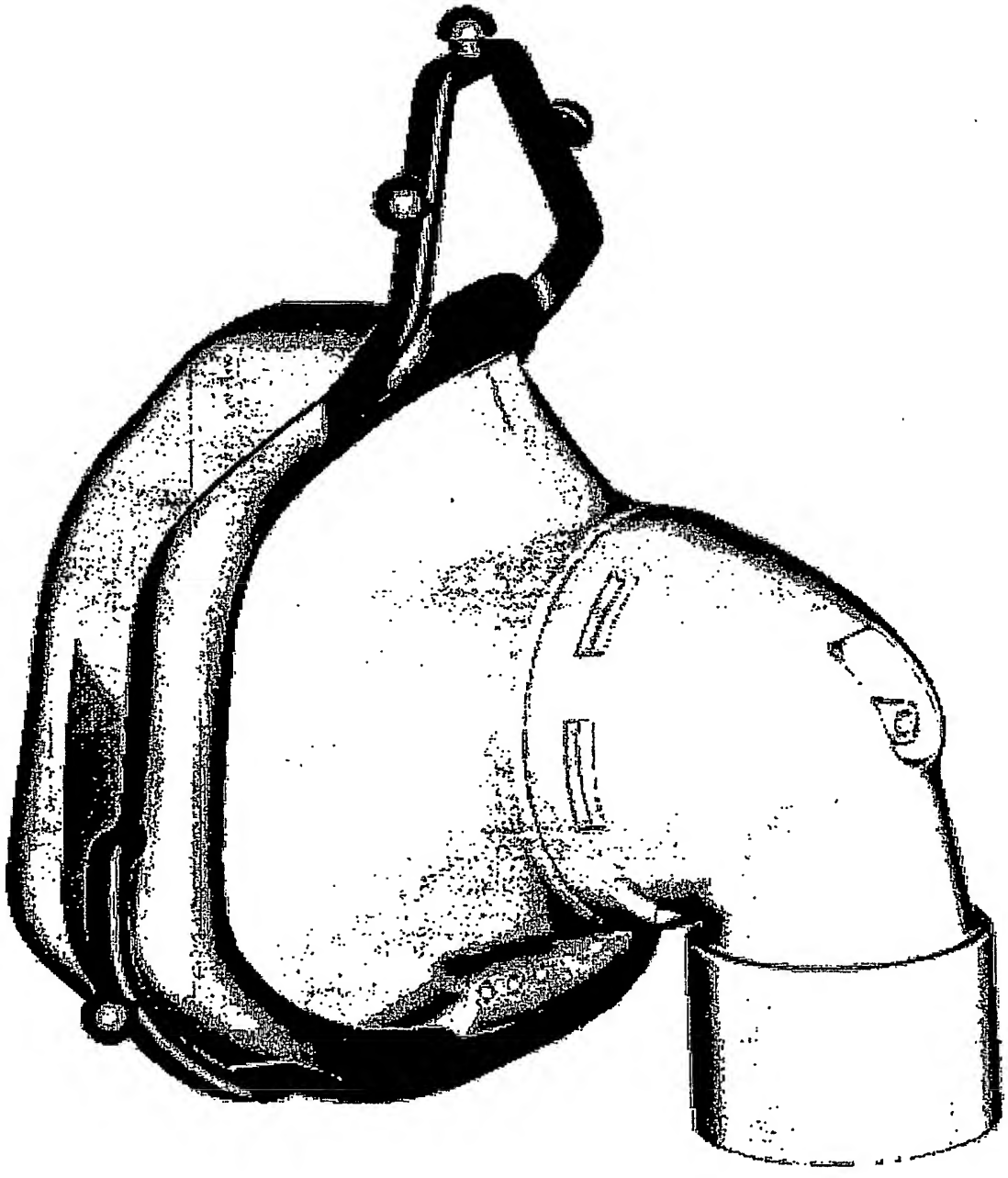

Fig. 10

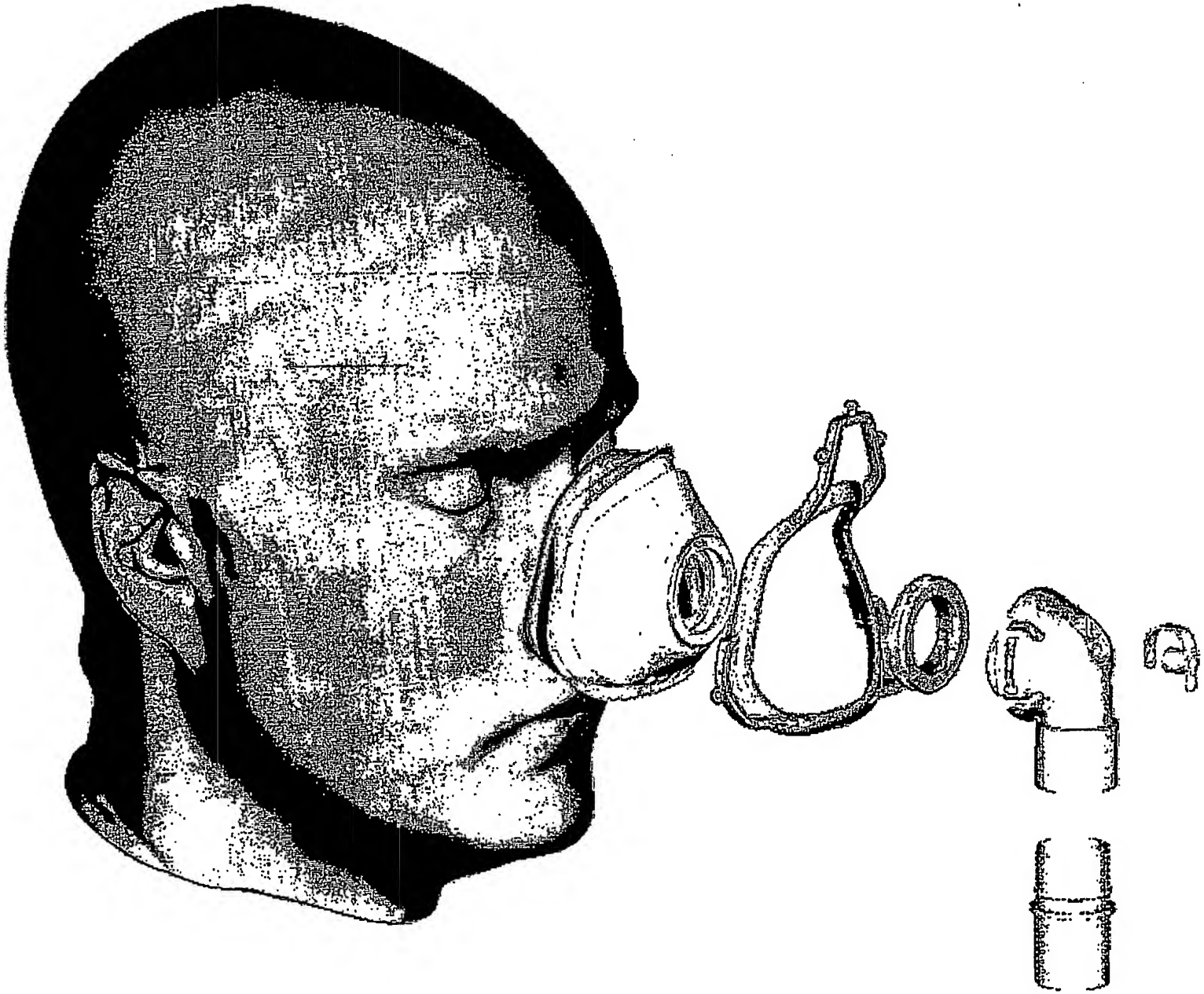

Fig. 11

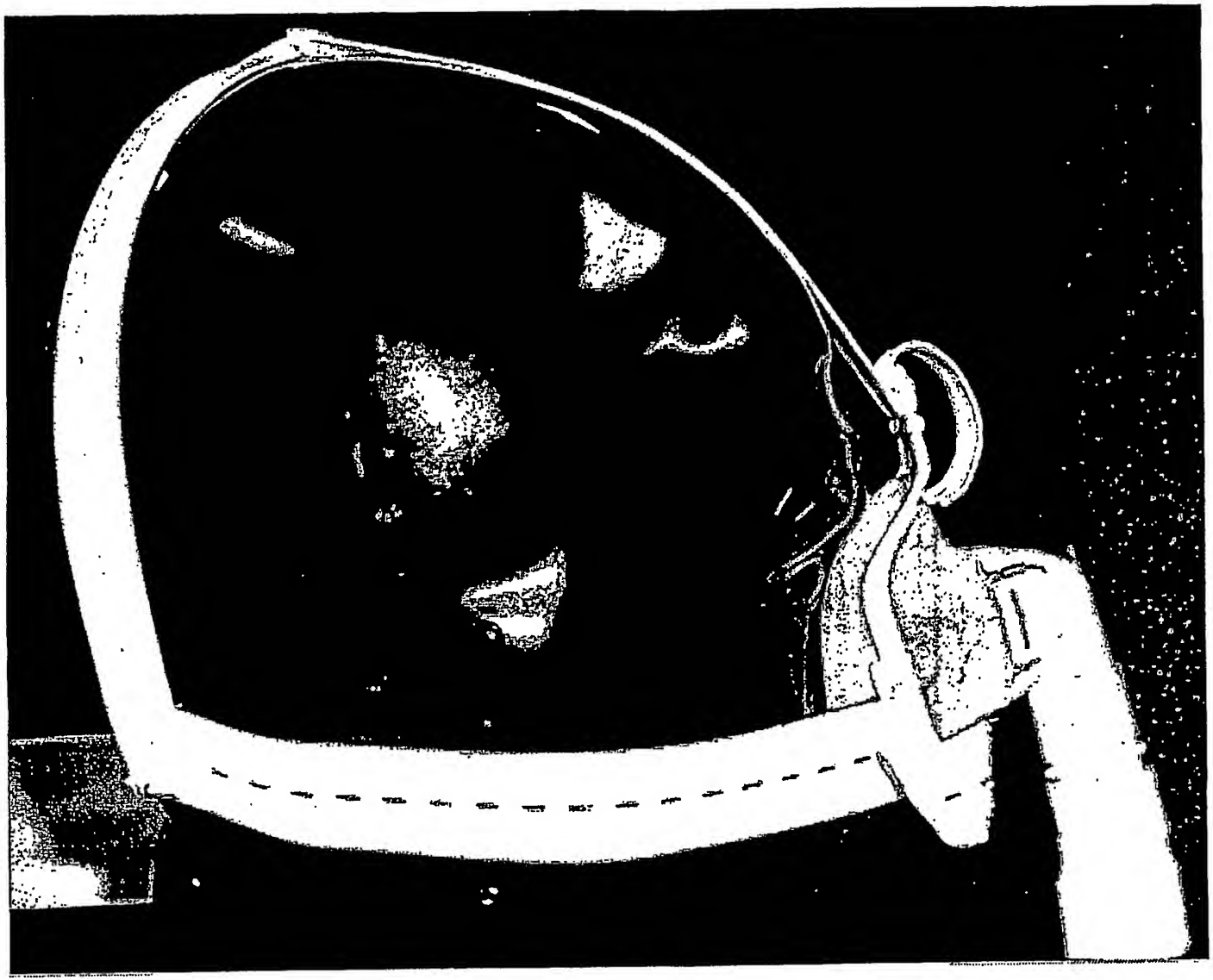

Fig. 12

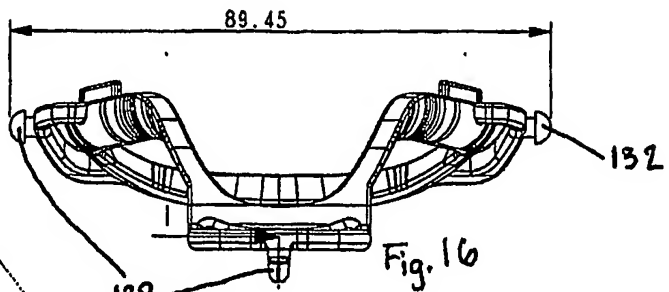

Fig. 16

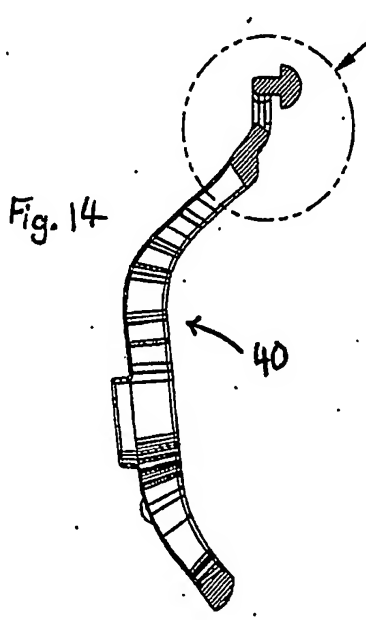

Fig. 14

SECTION 1-1

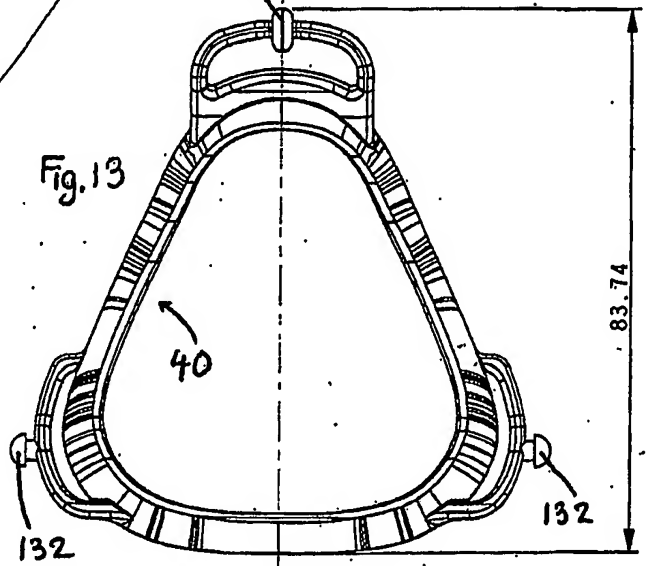

Fig. 13

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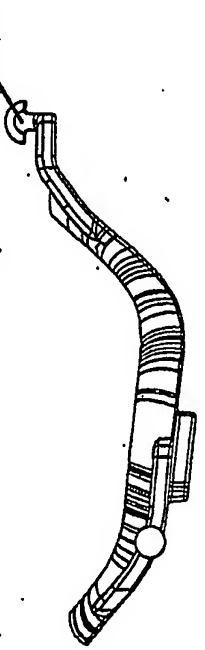


Fig. 15

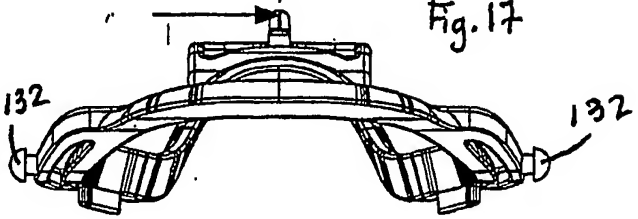
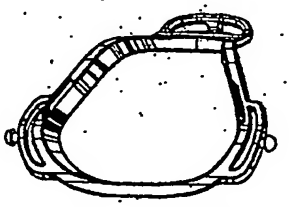
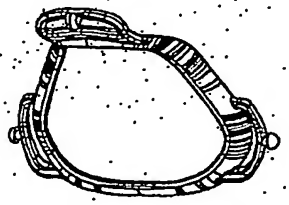


Fig. 17



SCALE 1:2

Fig. 19



SCALE 1:2.

Fig. 20

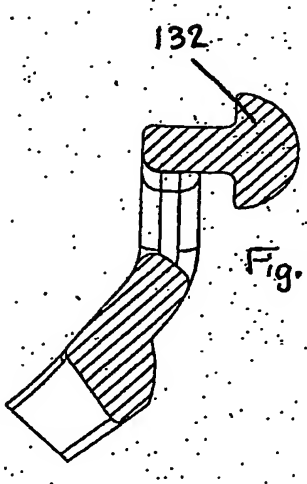


Fig. 18

DETAIL Z.
SCALE 3:1

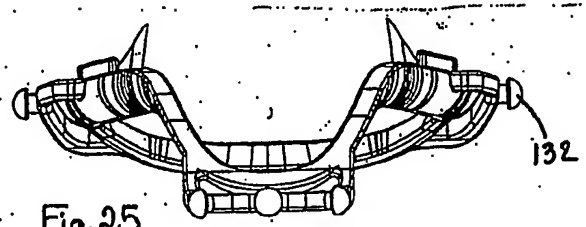


Fig. 25

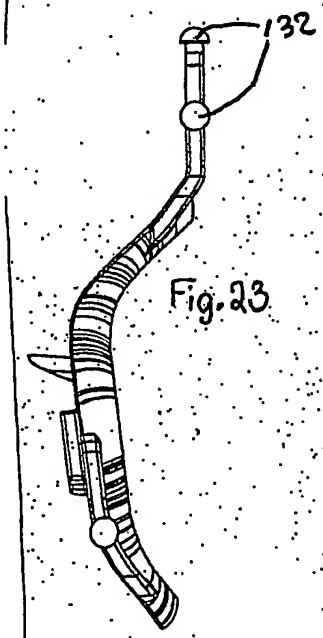


Fig. 23

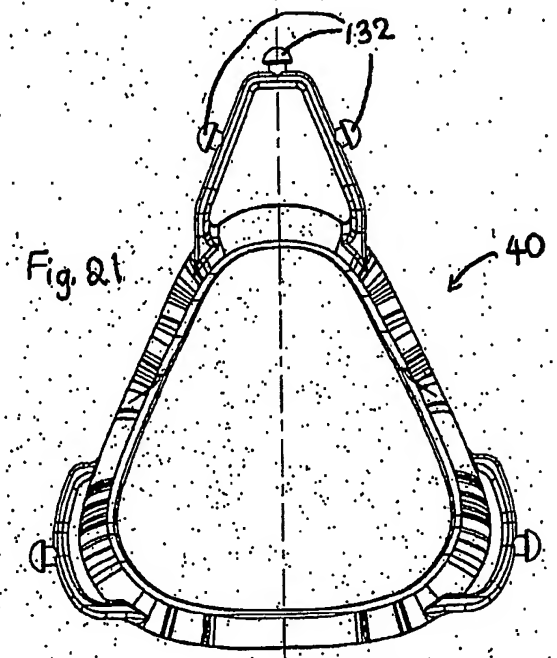


Fig. 21

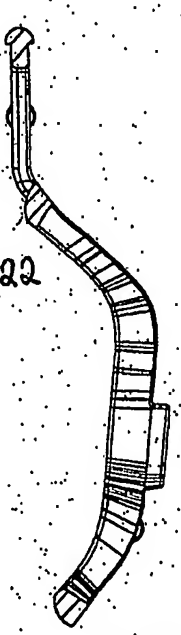


Fig. 22

SECTION 1-1

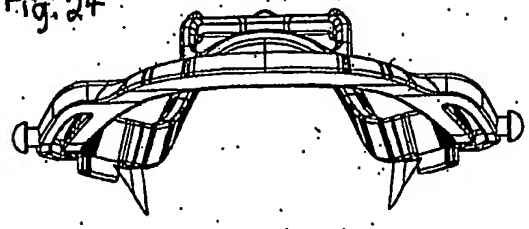


Fig. 24

Fig. 29

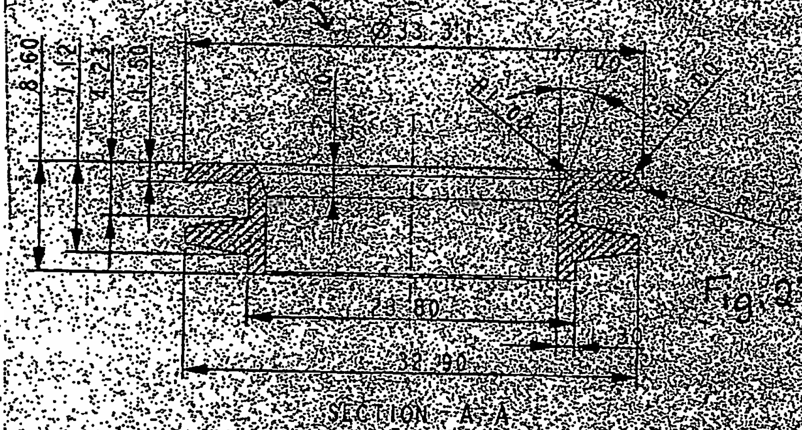


Fig. 27

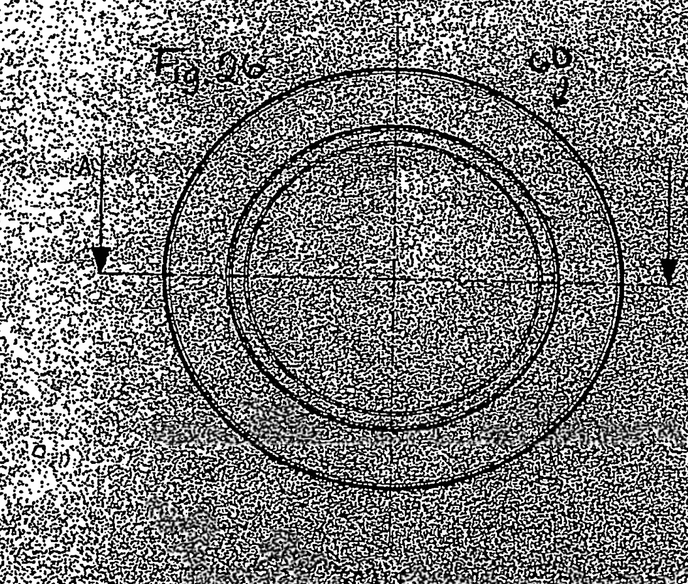


Fig. 26

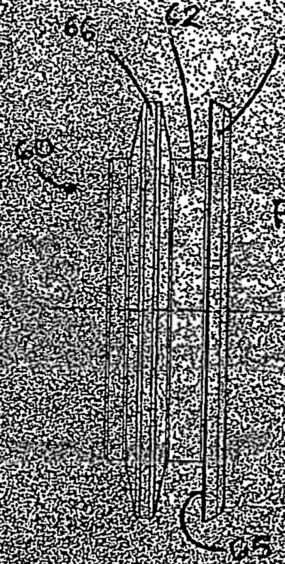


Fig. 28

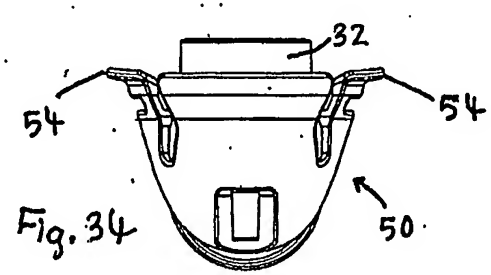


Fig. 34

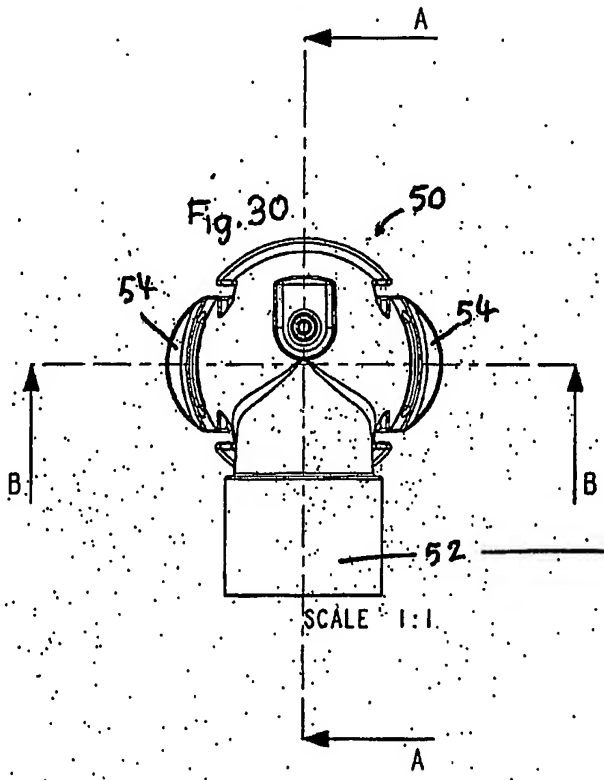


Fig. 30

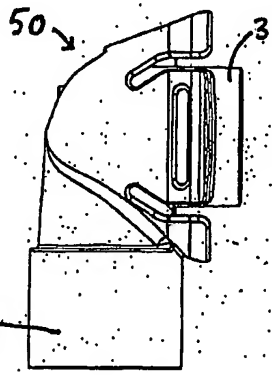


Fig. 31

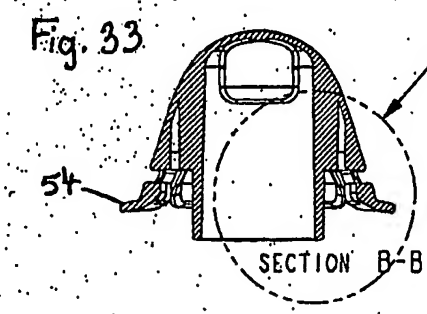


Fig. 33

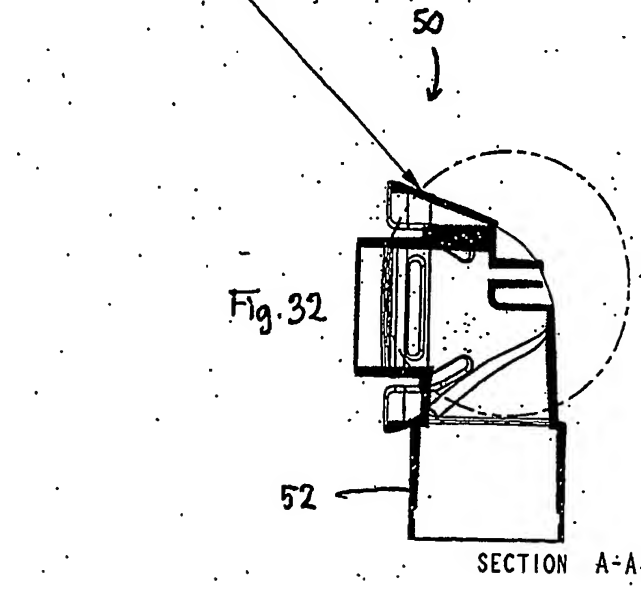


Fig. 32

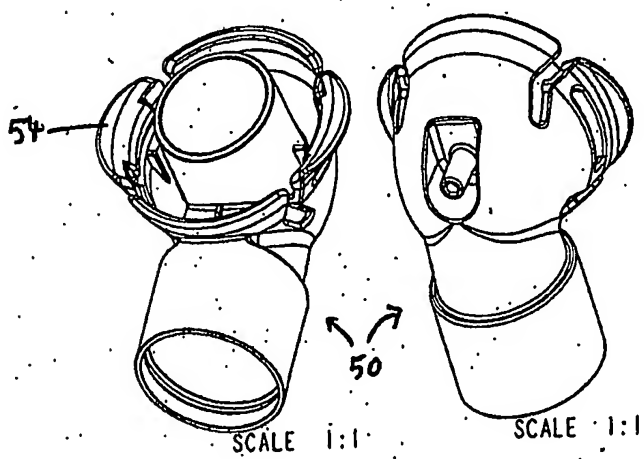


Fig. 35

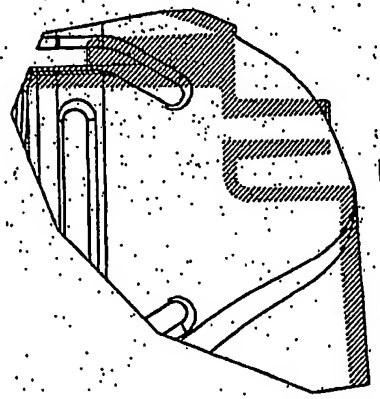


Fig. 37

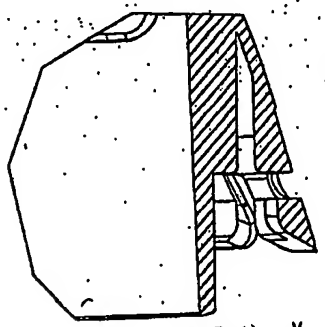
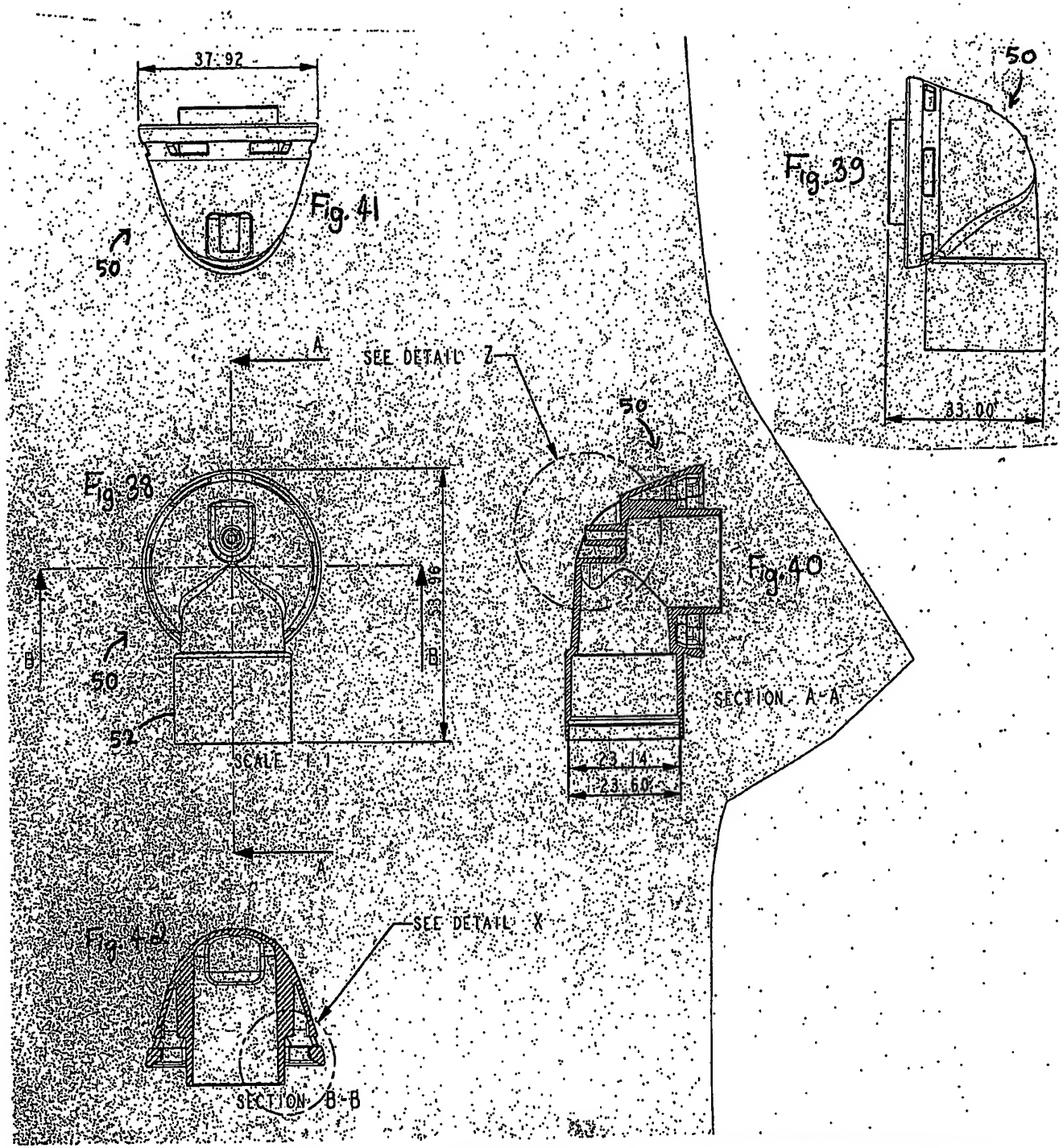


Fig. 36


37.92
50
Fig. 41
A
SEE DETAIL Z
50
Fig. 39
33.00
Fig. 38
50
52
SCALE 1
A
Fig. 40
SECTION A-A
23.14
23.60
Fig. 42
SEE DETAIL X
SECTION B-B

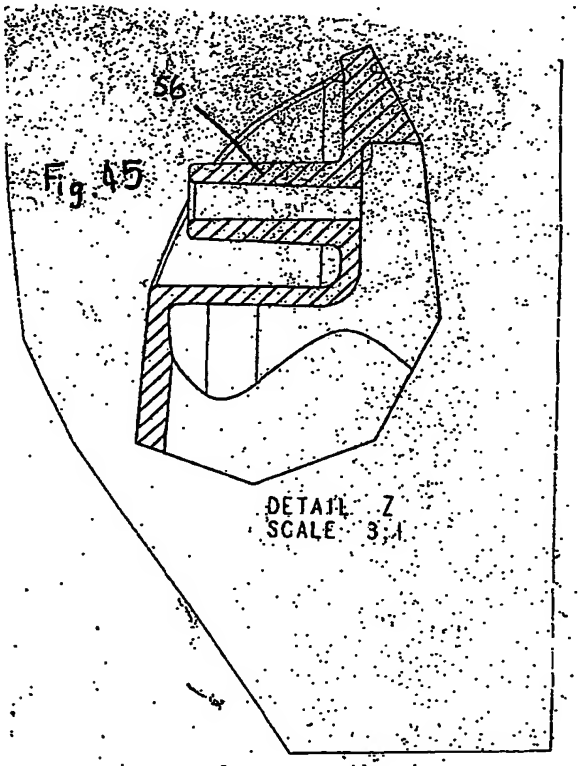


Fig. 45

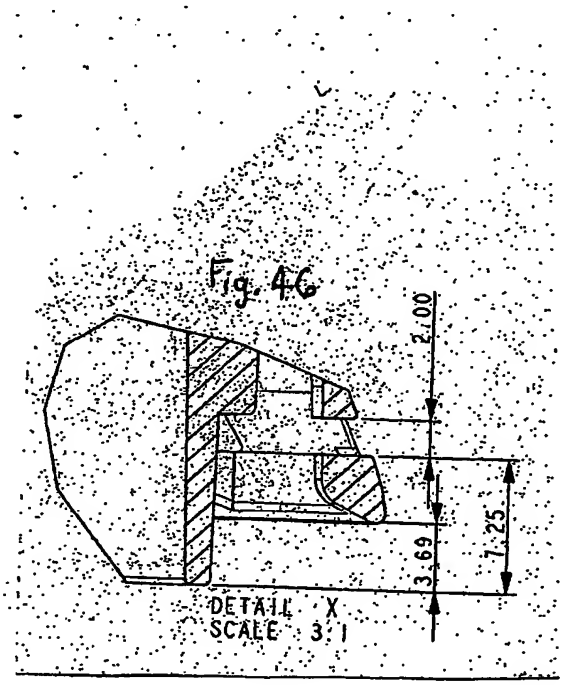


Fig. 46

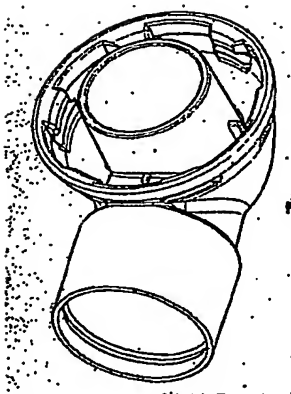


Fig. 43

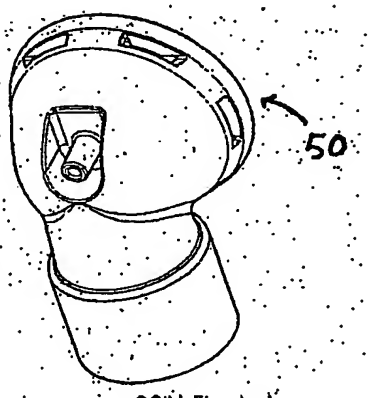


Fig. 44

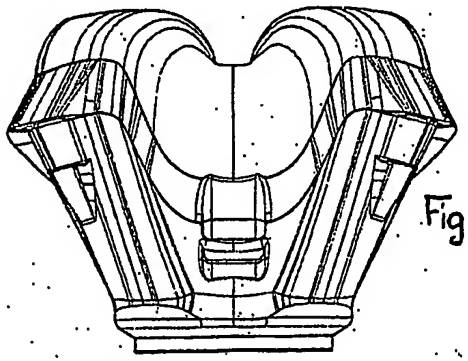
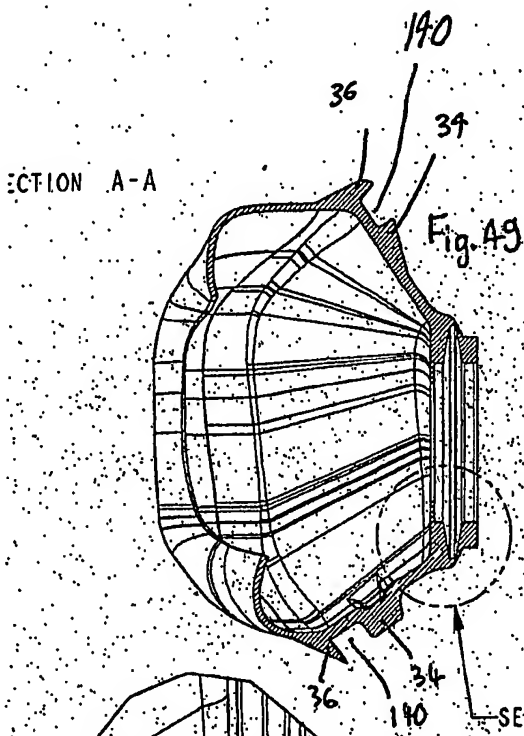


Fig. 50



ECTION A-A

Fig. 49

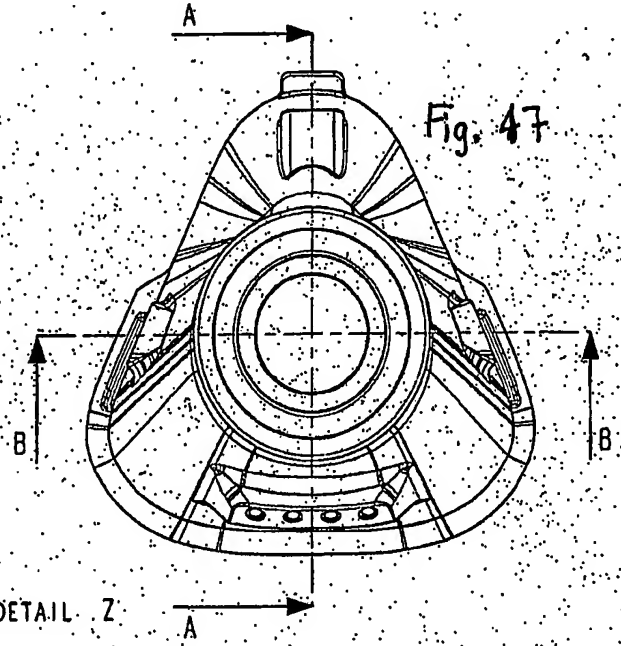


Fig. 47

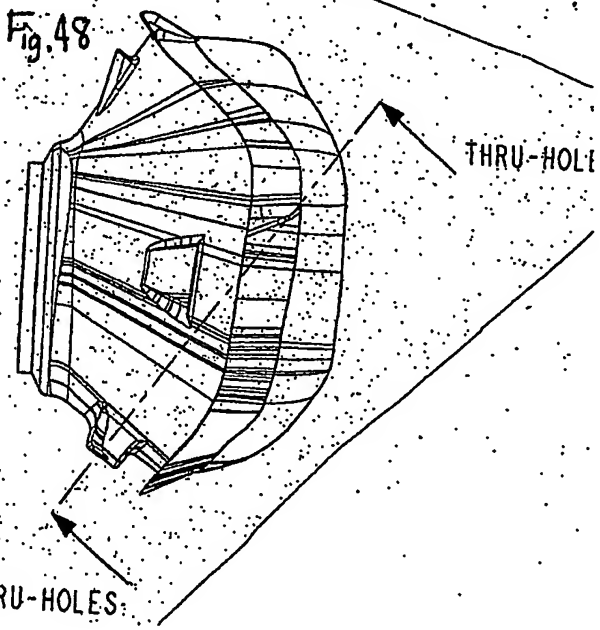


Fig. 48

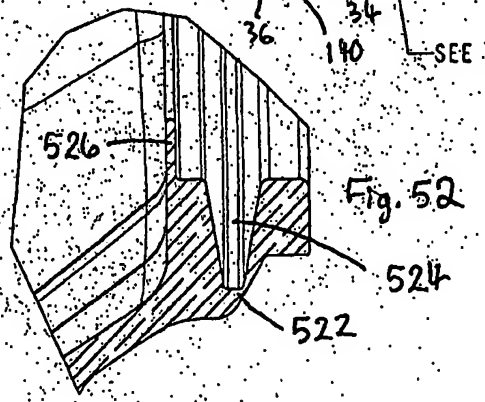


Fig. 52

DETAIL Z
SCALE 3:1

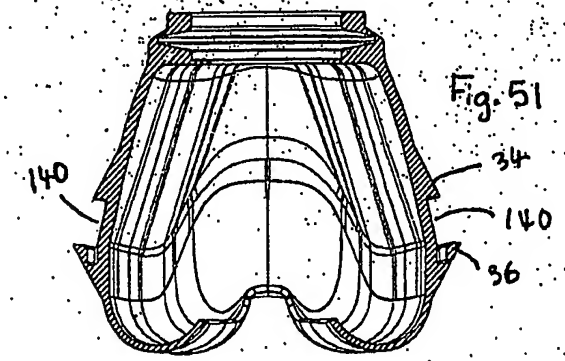


Fig. 51

SECTION B-B

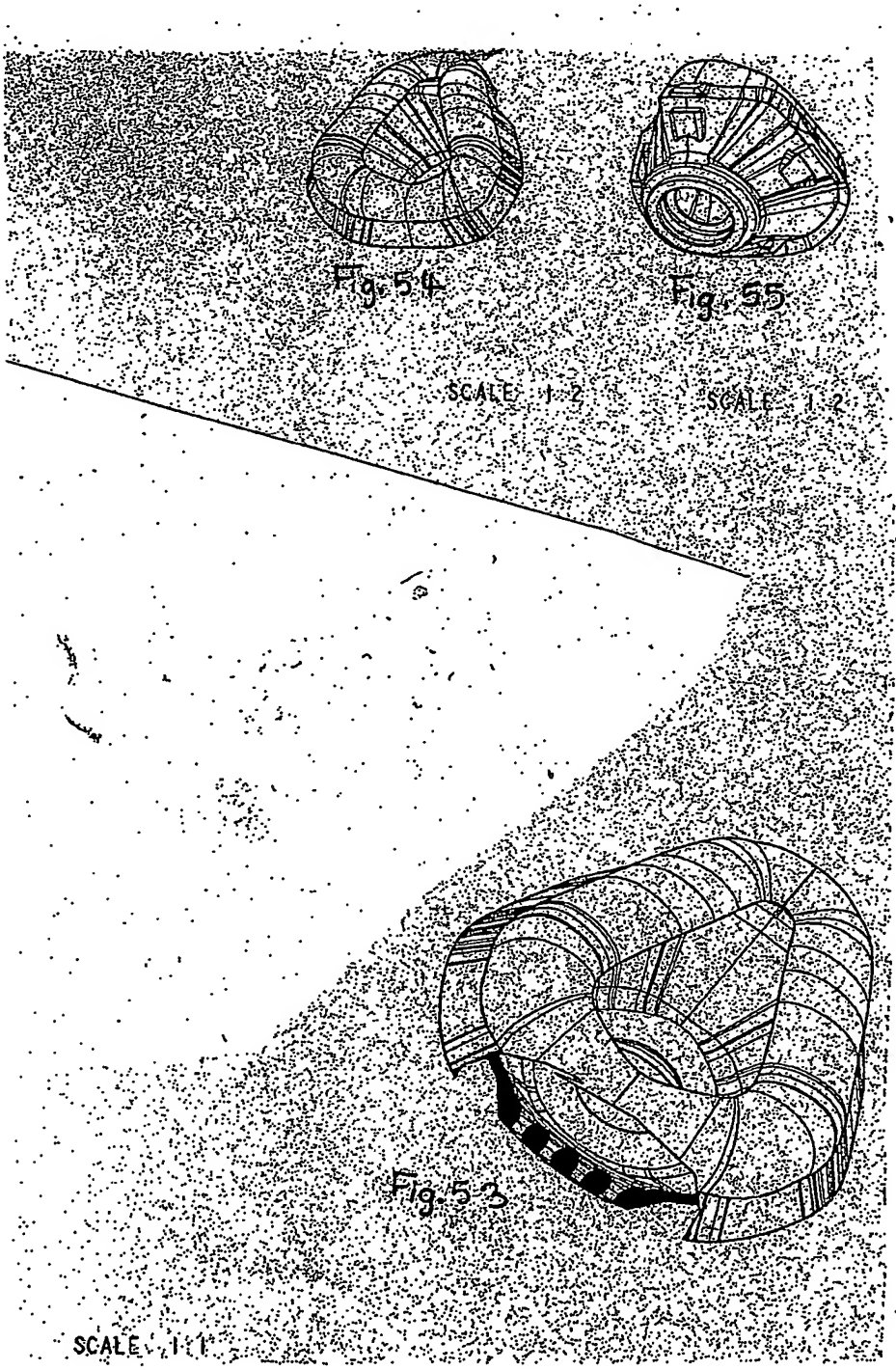


Fig. 54
Fig. 55
SCALE 1:2
SCALE 1:2
Fig. 53
SCALE 1:1

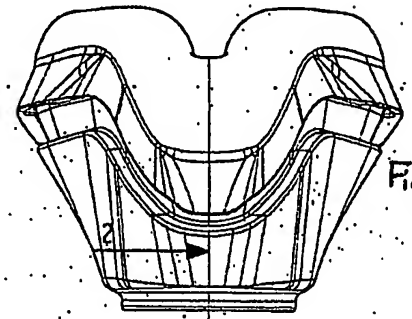


Fig. 59

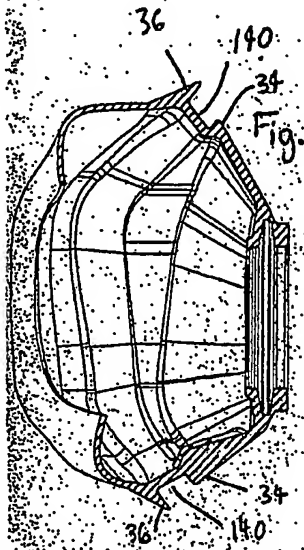


Fig. 58

SECTION 2-2

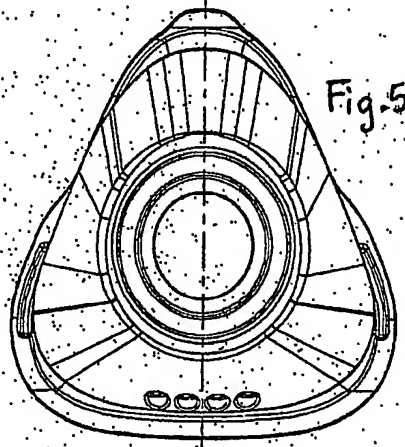


Fig. 56

SCALE 1:1

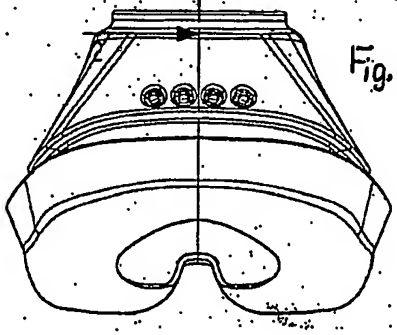


Fig. 60

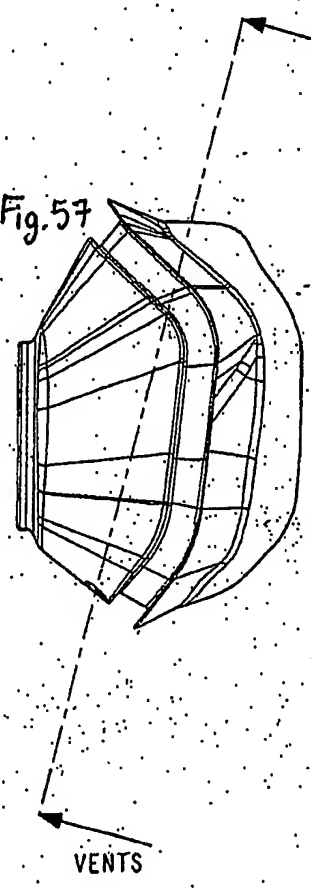


Fig. 57

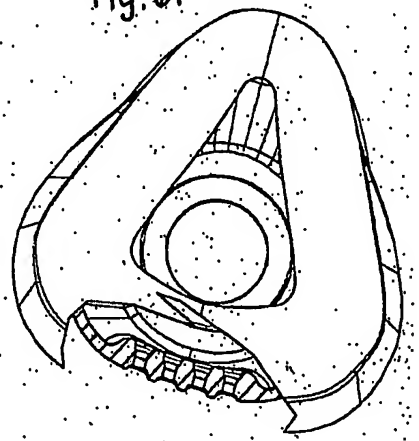


Fig. 61

SECTION VENTS

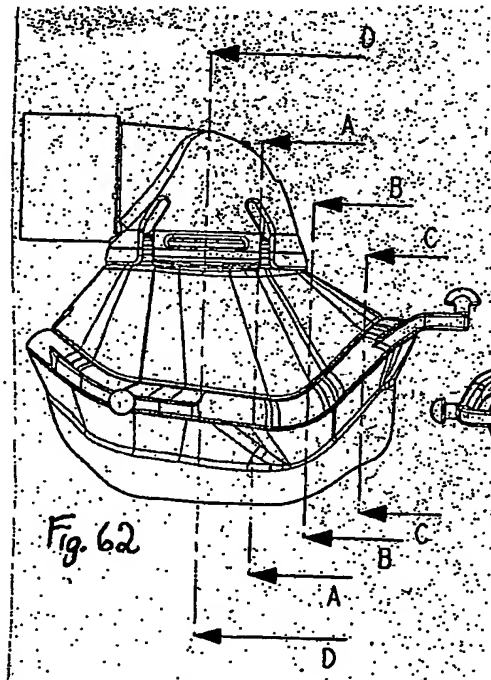


Fig. 62

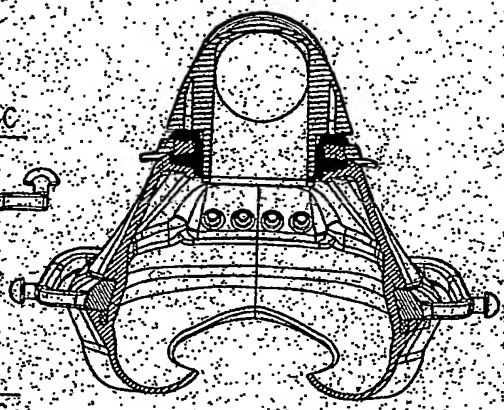


Fig. 63
SECTION D-D

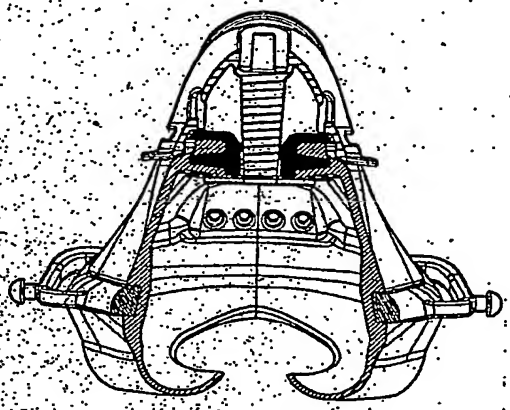


Fig. 64
SECTION A-A

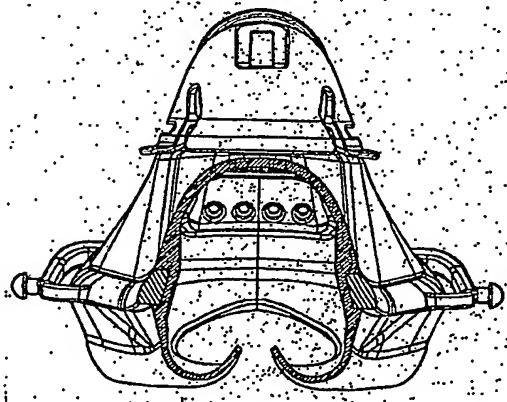


Fig. 65
SECTION B-B

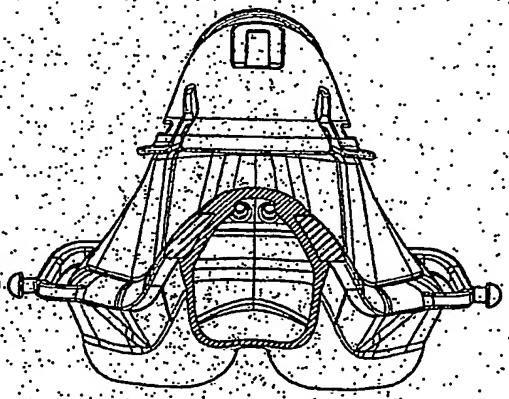


Fig. 66
SECTION C-C

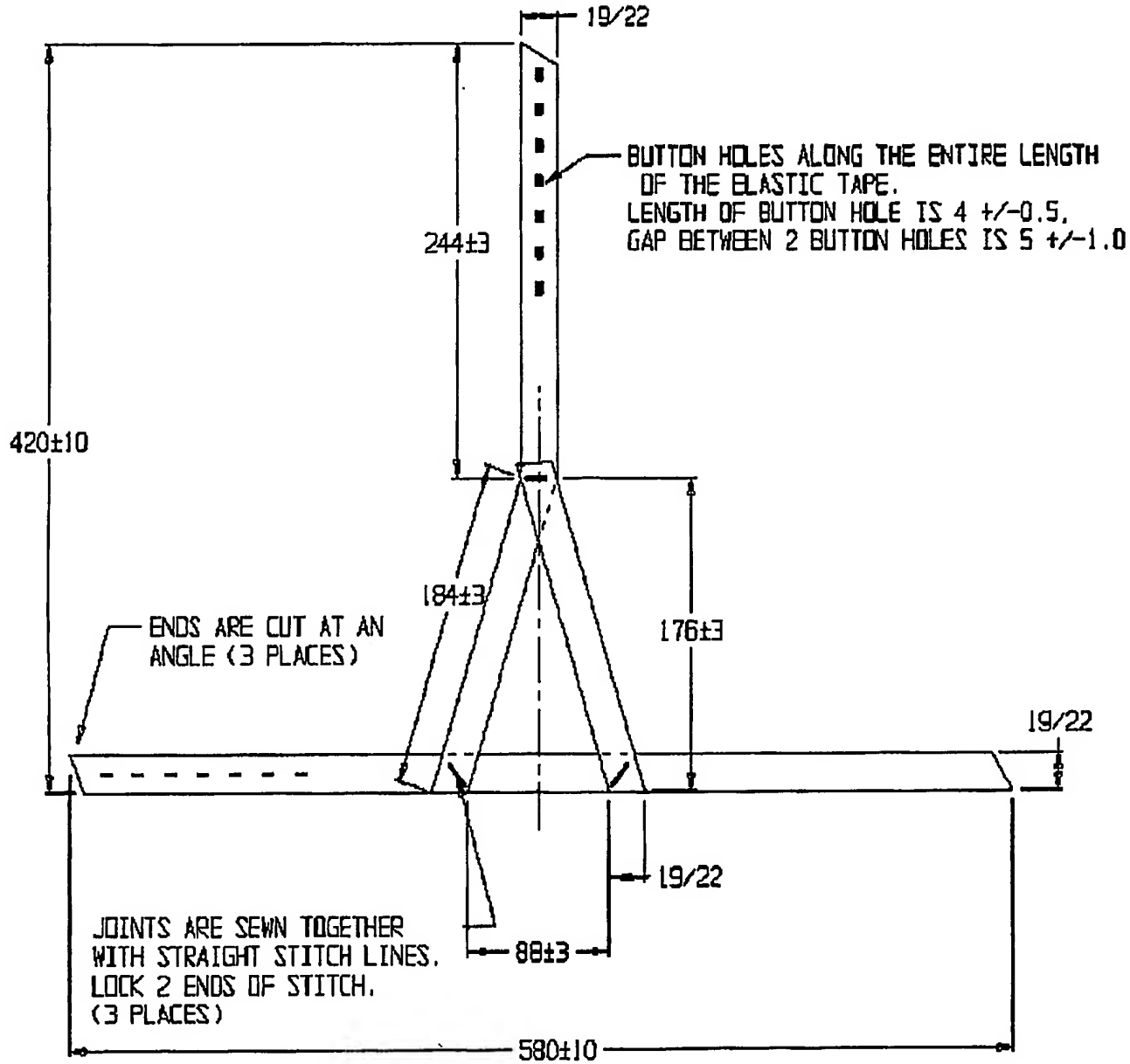

19/22
BUTTON HOLES ALONG THE ENTIRE LENGTH
OF THE ELASTIC TAPE.
LENGTH OF BUTTON HOLE IS 4 +/-0.5.
GAP BETWEEN 2 BUTTON HOLES IS 5 +/-1.0
244±3
420±10
184±3
176±3
ENDS ARE CUT AT AN
ANGLE (3 PLACES)
19/22
19/22
JOINTS ARE SEWN TOGETHER
WITH STRAIGHT STITCH LINES.
LOCK 2 ENDS OF STITCH.
(3 PLACES)
88±3
580±10

Fig. 67

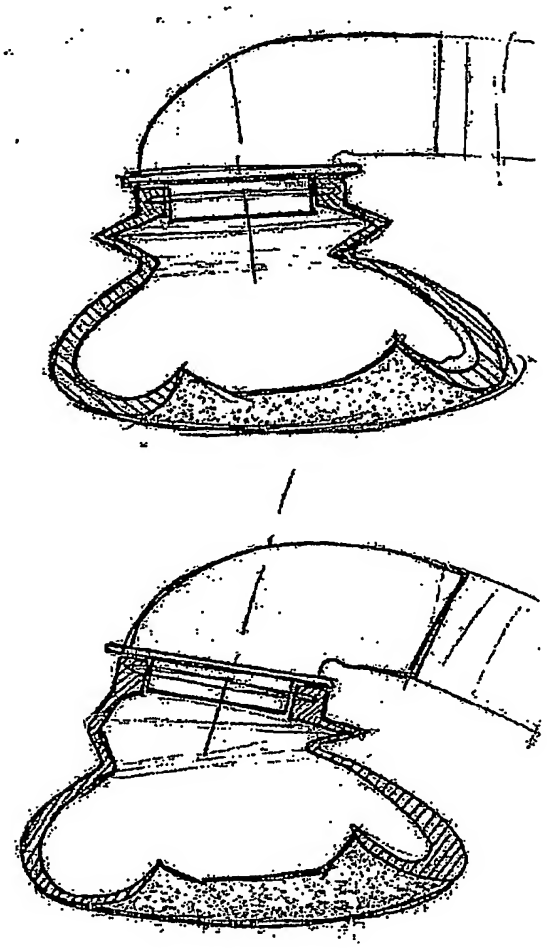


Fig. 68